REMARKS

The Office Action dated May 18, 2005 has been carefully considered. The claims have been amended in a manner which is believed to overcome the objections and rejections set forth in the Office Action.

Claims 19-22 and 27 were rejected as being directed to non-statutory subject matter. Claim 19 has been amended in the manner suggested by the Examiner and it is believed that this rejection is no longer applicable. Claims 20-22 have been amended to be method claims and thus not subject to this rejection. Claim 27, unlike claims 19-22 in their rejected form, is a method claim rather than a device claim. Thus, it is respectfully submitted that the rejection under 35 U.S.C. § 101 is inapplicable to this claim because it does not attempt to recite "structures being in contact with or implanted within the body", but rather the manner in which the stent is placed and then connected to a hydraulic driver placed in the chest through a sternotomy. It is believed that such recitation is permissible in a method claim.

Claims 18, 20, and 21 have been rejected as indefinite. Claim 18 has been cancelled and claims 20 and 21 have been amended to recite a method and to revise their dependency to claims 26 and 23, respectively. As amended, it is believed that these claims are no longer subject to the indefiniteness rejection.

Claims 19-21 were device claims rejected as not properly defining a process. It is believed that the amendment to claims 20 and 21 to convert them to method claims cures this rejection. Claim 19 has been amended to make it dependent on claim 17 rather than claim 18, which is believed to cure this rejection because the claim is now plainly a device and not a process claim. Although claim 22 was not rejected as an improper claim, it too has been amended in a manner consistent with the amendments to claims 20 and 21.

Claims 1-20 and 23-26 have been rejected as anticipated by Lederman Patent No. 6,210,318. It is respectfully submitted that, while the Lederman patent discloses a device having some first-impression similarity to that of the present invention, that similarity is superficial and that the invention claimed in the present application is fundamentally different from the device of Lederman. In order to bring this fundamental difference out more clearly, claim 1 has been amended to recite that the balloon is attached to a shell and that this shell is adapted to hold it in place against an inner wall of an arterial vessel. The device of Lederman is directed to essentially just the opposite. As recited in each of the independent claims of Lederman, the balloon is "unconnected to and separately positionable with respect to said stent", whereas the balloon of the present device is plainly recited as being "attached" to the shell. It is for this reason that Lederman discloses a "system" rather than a device, i.e., since the balloon and stent of Lederman are not connected to each other, they cannot properly be claimed as a device. This lack of attachment is readily apparent from figures 2A, 2B, 3A and 3B wherein the balloon 106 or 320 is centrally located in the lumen of stents 104, 250, 350 and 352. It is noted that valve 108, which is a balloon, does come into contact with the wall of stent 104, but it is not attached to that wall and is not a counterpulsation balloon as recited in claim 1, but rather a valve.

In contrast, the device claims of the present application are directed to a structure comprising a shell to which a balloon is attached. An example of such a structure is shown in transverse cross-section in figure 2 which illustrates shell 12, balloon 14 and frame 24. As stated at page 4, lines 30 and 31, the balloon 14 is peripherally attached to the periphery of the shell 12. Thus, balloon 14 defines an inflatable space 16 between it and the interior of the shell 12. This is an entirely different structure than the stent and balloon of Lederman which are not attached to

each other and which, in any event, do not include a shell which is adapted to be held against the inner wall of an arterial vessel as recited in the device claims in the present application.

As stated at page 6, lines 18-21, positioning and holding the shell of the device 10 against a wall of an aorta, the blood contacting surfaces of the device 10 are minimized because blood is not able to flow over the surfaces of the shell 12 which is adjacent the aorta wall. This minimization of surface area which can be contacted by the blood prevents blood clots from forming on the surface which the blood cannot reach. It is well known that blood clots will form on surface areas presented to the blood and the device of Lederman would expose a much larger surface to the blood than that of the present application. Furthermore, when the balloon of the present invention is deflated, it will be positioned adjacent the inner wall of the shell as shown in figure 2 which will reduce turbulence which would otherwise be caused if, as in the case of Lederman, there was a deflated balloon in the blood path. Once again, it is well known that turbulence in blood flow increases the likelihood of coagulation and the formation of blood clots. It is believed that the extensive discussion of Lederman with regard to claims 1-20 and 23-26 in the Office Action does not address the deficiency of the Lederman patent with regard to the recitation of a shell. It is recognized that claim 1, as previously presented, recited a "means for holding" which the Examiner may not have recognized as reciting the shell. Thus, it is believed that claim 1, and the claims dependent on it, are both clarified and broadened by reciting the "shell" rather than the "means for holding".

With regard to claims 21, 22 and 27, Kiyota Patent No. 5,453,076 does nothing to remedy the deficiency of Lederman with regard to the step of "holding a shell" having a balloon attached to it "against a wall of an arterial vessel." Thus, the combination of Lederman and Kiyota does not render claims 21, 22 and 27 unpatentable. In this regard, it is to be noted that claims 21 and

22 now recite a method rather than a device and are dependent, directly or indirectly, on claim 23. Indeed, the foregoing comments with regard to a rejection based on Lederman in view of Kiyota are equally applicable to all of method claims 21-27.

Newly added claims 28 and 29 are directed to a device and are dependent upon claim 1 and patentable for the same reasons as claim 1.

It is believed that all of the claims pending in the present application are patentable over the prior art of record. A favorable action is respectfully solicited.

The Commissioner is authorized to charge Orrick's Deposit Account No. 15-0665 in the amount of **$25.00** for the extra claim. The Commissioner is authorized to charge Orrick's Deposit Account No. **15-0665** for any fees required under 37 CFR §§ 1.16, 1.17 and 1.445 that are not covered, in whole or in part and credit any overpayments to said Deposit Account No. **15-0665**.

Respectfully submitted,
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